

CLAIMS

What is claimed is:

5 1. A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule.

10 2. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule.

15 3. The pharmaceutical composition of claims 1 or 2, wherein the composition is an aqueous solution or an oil solution.

20 4. The pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

25 5. The pharmaceutical composition of claim 4, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

6. The pharmaceutical composition of claim 5, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

7. The pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

8. The pharmaceutical composition of claim 7, wherein the oil-based solubilizing carrier molecule is lipiodol.

9. The pharmaceutical composition of claim 3, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

10. The pharmaceutical composition of claim 1, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

10

11. A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier, which when diluted with an aqueous solution for parenteral administration, remains substantially soluble in the aqueous solution.

15

12. The pharmaceutical composition of claim 11, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, is complexed with the pharmaceutically acceptable water solubilizing carrier.

20

13. The pharmaceutical composition of claim 11, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

25

14. The pharmaceutical composition of claim 13, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

15. The pharmaceutical composition of claim 14, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

30

16. The pharmaceutical composition of claim 11, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

5 17. The pharmaceutical composition of claim 16, wherein the oil-based solubilizing carrier molecule is lipiodol.

10 18. The pharmaceutical composition of claim 11, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

19. The pharmaceutical composition of claim 12, wherein the complex comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

15 20 21. The pharmaceutical composition of claim 11, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

22. A formulation of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein the formulation can be freeze-dried and when subsequently reconstituted in aqueous solution is substantially soluble.

25 26. The formulation of claim 21, wherein the Beta-lapachone, or a derivative or analog thereof is complexed with the pharmaceutically acceptable solubilizing carrier molecule.

27. The formulation of claim 21, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

24. The formulation of claim 23, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

5 25. The formulation of claim 24, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

10 26. The formulation of claim 21, wherein the pharmaceutically solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

15 27. The formulation of claim 26, wherein the oil-based solubilizing carrier molecule is lipiodol.

20 28. The formulation of claim 21, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

25 29. The formulation of claim 21, wherein the Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

30. A kit for the treatment of a mammalian cancer comprising at least one vial containing Beta-lapachone, or a derivative or analog thereof, according to any one of claims 1, 11 or 21.

31. A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

32. The pharmaceutical composition of claim 31, wherein the composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, or a derivative or

analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule, and further comprises the second anticancer agent and a pharmaceutically acceptable carrier.

33. The pharmaceutical composition of claims 31 or 32, wherein the second anticancer agent  
5 is a taxane derivative.

34. The pharmaceutical composition of claim 33, wherein the taxane derivative is paclitaxel.

35. The pharmaceutical composition of claims 31 or 32, wherein the composition is an  
10 aqueous solution or an oil solution.

36. The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

37. The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial.

38. The pharmaceutical composition of claim 31, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, 25 polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

39. The pharmaceutical composition of claim 38, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

40. The pharmaceutical composition of claim 39, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

41. The pharmaceutical composition of claim 31, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

42. The pharmaceutical composition of claim 41, wherein the oil-based solubilizing carrier molecule is lipiodol.

10 43. The pharmaceutical composition of claim 35, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

44. The pharmaceutical composition of claim 31 wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable water solubilizing carrier molecule, and the second anticancer agent and the pharmaceutically acceptable carrier exist as an emulsion.

5 20 45. A kit for the treatment of a mammalian tumor comprising one or more vials containing a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule and further comprising, within in the same vial or a separate vial, a second anticancer agent.

46. The kit of claim 45, wherein the one or more vials contain a complex of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule and further comprising, within in the same vial or a separate vial, the second anticancer agent.

25 47. The kit of claims 45 or 46, wherein the second anticancer agent is a taxane derivative.

30 48. The kit of claim 47, wherein the taxane derivative is paclitaxel.

49. The kit of claims 45 or 46, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

50. The kit of claim 49, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

10 51. The kit of claim 50, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

52. The kit of claims 45 or 46, wherein the solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

15 53. The kit of claim 52, wherein the oil-based solubilizing carrier molecule is lipiodol.

54. The kit of claims 45 or 46, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

20 55. A method for treating cancer comprising administering to a patient a pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule.

56. The method of claim 55, wherein the pharmaceutical composition comprises a complex 25 or solution of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule.

57. The method of claims 55 or 56, wherein the composition is an aqueous solution or an oil solution.

58. The method of claim 55, where the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

5 59. The method of claim 58, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

10 60. The method of claim 59, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

15 61. The method of claim 55, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

62. The method of claim 61, wherein the oil-based solubilizing carrier molecule is lipiodol.

63. The method of claim 57, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

20 64. The method of claim 55, wherein the pharmaceutical composition is administered parenterally.

25 65. The method of claim 64, wherein the pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

30 66. The method of claim 55, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

67. A method for treating cancer comprising administering to a patient a pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, which when  
5 diluted with an aqueous solution for parenteral administration, remains substantially soluble in the aqueous solution.

68. The method of claim 67, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, is complexed with the pharmaceutically acceptable solubilizing  
10 carrier.

69. The method of claim 67, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.  
15

70. The method of claim 69, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.  
20

71. The method of claim 70, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.  
25

72. The method of claim 67, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.  
25

73. The method of claim 72, wherein the oil-based solubilizing carrier molecule is lipiodol.  
30

74. The method of claim 67, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

75. The method of claim 67, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable water solubilizing carrier molecule exist as an emulsion.

5

76. A method for treating cancer comprising administering to a patient a formulation of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable, solubilizing carrier molecule, wherein the complex can be freeze-dried and when subsequently reconstituted in aqueous solution is substantially soluble.

10

77. The method of claim 76, wherein the Beta-lapachone, or a derivative or analog thereof, is complexed with the pharmaceutically acceptable, solubilizing carrier.

15  
20  
25

78. The method of claim 76, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

79. The method of claim 78, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

80. The method of claim 79, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

25

81. The method of claim 76, wherein the pharmaceutically acceptable solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

30

82. The method of claim 81, wherein the oil-based solubilizing carrier molecule is lipiodol.

83. The method of claim 76, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

84. The method of claim 76, wherein the formulation is administered parenterally.

5

85. The method of claim 84, wherein said pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

10 86. The method of claim 76, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

15 87. A method for treating cancer comprising administering to a patient a pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable, solubilizing carrier molecule, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

20 88. The method of claim 87, wherein the pharmaceutical composition comprises a complex of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable, solubilizing carrier molecule, and further comprising the second anticancer agent and a pharmaceutically acceptable carrier.

25 89. The method of claim 87 or 88, wherein the second anticancer agent is a taxane derivative.

90. The method of claim 89, wherein the taxane derivative is paclitaxel.

91. The method of claims 87 or 88, wherein the composition is an aqueous solution or an oil solution.

30

92. The method of claim 87, wherein said therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is admixed with the second taxane derivative and the pharmaceutically acceptable carrier and contained in a single vial.

5

93. The method of claim 87, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial, the contents of the first and second vial being administered simultaneously or sequentially.

10

94. The method of claim 87, wherein the solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

15

95. The method of claim 94, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

20

96. The method of claim 95, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

25

97. The method of claim 87, wherein the solubilizing carrier molecule is an oil-based stabilizing carrier molecule.

98. The method of claim 97, wherein the oil-based solubilizing carrier molecule is lipiodol.

25

99. The method of claim 91, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

30

100. The method of claim 87, wherein the pharmaceutical composition is administered parenterally.

5 101. The method of claim 87, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable water solubilizing carrier molecule, and the anticancer agent and the pharmaceutically acceptable carrier exist as an emulsion.

10 102. A method for treating cancer comprising administering to a patient a pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, which when diluted with an aqueous solution for parenteral administration, remains substantially soluble in the aqueous solution, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

15 103. The method of claim 102, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, in the pharmaceutical composition is complexed with the pharmaceutically acceptable solubilizing carrier molecule, which when diluted with the aqueous solution for parenteral administration, remains substantially soluble in the aqueous solution.

20 104. The method of claim 102, wherein the second anticancer agent is a taxane derivative.

25 105. The method of claim 104, wherein the taxane derivative is paclitaxel.

106. The method of claim 102, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

30

107. The method of claim 102, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the  
5 pharmaceutically acceptable carrier are contained in a second vial, the contents of the first and second vial being administered simultaneously or sequentially.

108. The method of claim 102, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of  
10 Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

109. The method of claim 108, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.  
15

110. The method of claim 109, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

111. The method of claim 102, wherein the solubilizing carrier molecule is an oil-based  
20 solubilizing carrier molecule.

112. The method of claim 111, wherein the oil-based solubilizing carrier molecule is lipiodol.

25 113. The method of claim 102, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

114. The method of claim 102, wherein the pharmaceutical composition comprises a dosage  
unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to  
30 once every four weeks.

115. The method of claim 102, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule, and the second anticancer agent and the pharmaceutically acceptable carrier exist as an emulsion.

116. A method for treating cancer comprising administering to a patient a formulation of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein the formulation can be freeze-dried and when subsequently 10 reconstituted in aqueous solution is substantially soluble, the formulation further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

117. The method of claim 116, wherein the Beta-lapachone, or a derivative or analog thereof, in the formulation is complexed with the pharmaceutically acceptable solubilizing carrier.

118. The method of claim 116, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable, solubilizing carrier molecule is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

119. The method of claim 116, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial, the contents of the first and 25 second vial being administered simultaneously or sequentially.

120. The method of claim 116, wherein the pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene

glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

121. The method of claim 120, wherein the water-solubilizing carrier molecule is beta-  
5 cyclodextrin.

122. The method of claim 121, wherein the beta-cyclodextrin is hydroxypropyl-beta-  
cyclodextrin.

10 123. The method of claim 116, wherein the solubilizing carrier molecule is an oil-based  
stabilizing carrier molecule.

124. The method of claim 123, wherein the oil-based solubilizing carrier molecule is lipiodol.

15 125. The method of claim 116, wherein the concentration of Beta-lapachone in solution is at  
least 1 mg/ml.

126. The method of claim 116, wherein the anticancer agent is a taxane derivative.

20 127. The method of claim 126, wherein the taxane derivative is paclitaxel.

128. The method of claim 116, wherein the therapeutically effective amount of Beta-  
lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing  
carrier molecule, and the second anticancer agent and the pharmaceutically acceptable carrier  
25 exist as an emulsion.

129. A method for treating cancer comprising first administering to a patient a pharmaceutical  
composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or  
analog thereof, and a solubilizing carrier molecule, and subsequently subjecting said patient to  
30 radiation therapy.

130. The method of claim 129, wherein said pharmaceutically acceptable solubilizing carrier molecule is a water-solubilizing carrier molecule selected from the group consisting of Poloxamer, Povidone K17, Povidone K12, Tween 80, ethanol, Cremophor/ethanol, polyethylene 5 glycol (PEG) 400, propylene glycol, Trappsol, alpha-cyclodextrin or analogs thereof, beta-cyclodextrin or analogs thereof, and gamma-cyclodextrin or analogs thereof.

131. The method of claim 130, wherein the water-solubilizing carrier molecule is beta-cyclodextrin.

10

132. The method of claim 131, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

15

133. The method of claim 129, wherein the solubilizing carrier molecule is an oil-based solubilizing carrier molecule.

20

134. The method of claim 133, wherein the oil-based solubilizing carrier molecule is lipiodol.

135. The method of claim 129, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

25

136. The method of claim 129, wherein said pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

25

137. The method of claim 129, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule exist as an emulsion.

138. A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, formulated with a pharmaceutically acceptable fat emulsion vehicle to form an emulsion suitable for parenteral administration.

5 139. The pharmaceutical composition of claim 138, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

140. The pharmaceutical composition of claim 138, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

10 141. The pharmaceutical composition of claim 138, wherein the emulsion comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

15 142. A formulation of Beta-Lapachone, or a derivative or analog thereon, and a pharmaceutically acceptable fat emulsion vehicle, wherein the formulation can be freeze-dried and when subsequently reconstituted is substantially soluble.

20 143. The formulation of claim 142, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

144. The formulation of claim 142, wherein the concentration of Beta-Lapachone in the formulation is at least 1mg/kg.

25 145. A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, formulated with a pharmaceutically acceptable fat emulsion vehicle to form an emulsion suitable for parenteral administration, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

146. The pharmaceutical composition of claim 145, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

147. The pharmaceutical composition of claim 145, wherein the second anticancer agent is a  
5 taxane derivative.

148. The pharmaceutical composition of claim 147, wherein the taxane derivative is paclitaxel.

10 149. The pharmaceutical composition of claim 145, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

150. The pharmaceutical composition of claim 145, wherein the emulsion comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

151. The pharmaceutical composition of claim 145, wherein the emulsion comprising the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable fat emulsion vehicle is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

152. The pharmaceutical composition of claim 145, wherein the emulsion comprising the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable fat emulsion vehicle is contained in a first vial, and the second  
25 anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial.

153. A kit for the treatment of a mammalian cancer comprising at least one vial containing Beta-lapachone, or a derivative or analog thereof, according to any one of claims 138, 142 or 145.

154. A kit for the treatment of a mammalian tumor comprising one or more vials containing an emulsion comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable fat emulsion vehicle, and further comprising, within in the same vial or a separate vial, a second anticancer agent.

5

155. The kit of claim 154, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

156. The kit of claim 154, wherein the second anticancer agent is a taxane derivative.

10

157. The kit of claim 156, wherein the taxane derivative is paclitaxel

158. The kit of claim 154, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

15

159. A method for treating cancer comprising administering to a patient a pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable fat emulsion vehicle for parenteral administration.

20

160. The method of claim 159, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

25

161. The method of claim 159, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

162. The method of claim 159, wherein the emulsion comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

30

163. A method for treating cancer comprising administering to a patient an emulsion comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, formulated in a pharmaceutically acceptable fat emulsion vehicle for parenteral administration, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

5

164. The method of claim 163, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

10 165. The method of claim 163, wherein the second anticancer agent is a taxane derivative.

166. The method of claim 165, wherein the taxane derivative is paclitaxel.

15 167. The method of claim 163, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

20 168. The method of claim 163, wherein the emulsion comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

25 169. A method for treating cancer comprising first administering to a patient an emulsion comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, formulated in a pharmaceutically acceptable fat emulsion vehicle, and subsequently subjecting the patient to radiation therapy.

25

170. The method of claim 169, wherein the pharmaceutically acceptable fat emulsion vehicle is Intralipid®.

30 171. The method of claim 169, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

172. The method of claim 169, wherein the emulsion comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

5

173. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein the cancer is characterized by the presence of one or more solid tumors.

174. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein 10 the cancer is prostate cancer.

175. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein the cancer is multiple myeloma.

176. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein the cancer is a hematologic tumor.

177. The method of claim 151, wherein the cancer is a lymphoid tumor.

178. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein 20 the cancer is ovarian cancer.

179. The method of any one of claims 55, 67, 76, 87, 102, 116, 129, 159, 163 or 169, wherein the cancer is breast cancer.

180. A sterile injectable pharmaceutical composition for intravenous administration 25 comprising a complex of a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable water-solubilizing carrier molecule.

181. The sterile injectable pharmaceutical composition of claim 180, wherein the composition is in aqueous solution.

182. The sterile injectable pharmaceutical composition of claim 180, wherein the 5 pharmaceutically acceptable, water solubilizing carrier molecule is hydroxypropyl-beta-cyclodextrin.

183. The sterile injectable pharmaceutical composition of claim 180, further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

10

184. The sterile injectable pharmaceutical composition of claim 183, wherein the second anticancer agent is a taxane derivative.

15

185. The sterile injectable pharmaceutical composition of claim 184, wherein the taxane derivative is paclitaxel.

20

186. The sterile injectable pharmaceutical composition of claim 180, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

187. The sterile injectable pharmaceutical composition of claim 180, wherein said pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

25

188. The sterile injectable pharmaceutical composition of claim 180, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable water solubilizing carrier molecule exist as an emulsion.

30

189. A sterile injectable pharmaceutical composition for intravenous administration comprising a complex of a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable oil-based solubilizing carrier molecule.

190. The sterile injectable pharmaceutical composition of claim 189, wherein the pharmaceutically acceptable, oil-based solubilizing carrier molecule is lipiodol.

5 191. The sterile injectable pharmaceutical composition of claim 189, further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

192. The sterile injectable pharmaceutical composition of claim 191, wherein the second anticancer agent is a taxane derivative.

10

193. The sterile injectable pharmaceutical composition of claim 192, wherein the taxane derivative is paclitaxel.

15 194. The sterile injectable pharmaceutical composition of claim 189, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

20 195. The sterile injectable pharmaceutical composition of claim 189, wherein said pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

25 196. The sterile injectable pharmaceutical composition of claim 189, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable water solubilizing carrier molecule exist as an emulsion.

197. A sterile injectable pharmaceutical composition for intravenous administration comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, in a pharmaceutically acceptable fat emulsion vehicle.

30 198. The sterile injectable pharmaceutical composition of claim 197, wherein the fat emulsion is Intralipid®.

199. The sterile injectable pharmaceutical composition of claim 197, further comprising an anticancer agent and a pharmaceutically acceptable carrier.

5 200. The sterile injectable pharmaceutical composition of claim 197, wherein the anticancer agent is a taxane derivative.

201. The sterile injectable pharmaceutical composition of claim 200, wherein the taxane derivative is paclitaxel.

10 202. The sterile injectable pharmaceutical composition of claim 197, wherein the concentration of Beta-lapachone in the emulsion is at least 1 mg/ml.

15 203. The sterile injectable pharmaceutical composition of claim 197, wherein the pharmaceutical composition comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.